

***Radius Health, Inc. and Ipsen Pharma S.A.S. v. Orbicular Pharmaceutical Technologies Private Limited*, C.A. No. 22-11546-RGS**
Exhibit A: Joint Claim Construction Statement

I. Agreed-Upon Construction

No.	Term	Construction
1	“storage-stable composition” / “storage stable composition” U.S. Patent No. 8,148,333 (“333 patent”): Claims 1-5, 8-13 U.S. Patent No. 8,748,382 (“382 patent”): Claims 1, 5, 6	A composition where the amount, purity of the PTHrP remains above about 95% of the original amount under one of the following conditions: (1) storage for over 2 years at 5° C.; or (2) storage for over 30 days at 25° C.
2	“buffer” U.S. Patent No. RE49,444 (“444 patent”): Claims 2, 22, 64 '333 patent: Claim 1 '382 patent: Claim 1	Any acid or salt combination which is pharmaceutically acceptable and capable of maintaining the composition of the present invention within a desired pH range.

II. Disputed Constructions

No.	Term¹	Plaintiffs' Construction	Defendant's Construction	Court's Construction
3	<p>“wherein the suitability of the formulated abaloparatide drug product for administration to a subject has been established by a method comprising: detecting and quantifying the presence of $\leq 5\%$ w/w beta-Asp10 of the total peptide content in the formulated abaloparatide drug product.”</p> <p>U.S. Patent No. 10,996,208 (“208 patent”): Claims 14, 15</p>	Plain and ordinary meaning ²	The detection and quantification of beta-Asp10 is determined using a method comprising an aqueous buffer wherein said aqueous buffer has a pH range of between 6-10 prior to mixing with any additional mobile phase solvent(s).	
4	<p>“a plasma C_{\max}”³</p> <p>'444 patent: Claims 10, 13, 14, 69, 74, 75</p>	Not indefinite; plain and ordinary meaning	Indefinite	
5	<p>“a plasma $t_{1/2}$”</p> <p>'444 patent: Claims 12, 14, 69, 72, 74, 77</p>	Not indefinite; plain and ordinary meaning	Indefinite	

¹ Cited claims in which each term appears are illustrative. The claim term may appear in additional claims.

² Defendant states that in the Parties’ “meet and confer” on May 18, 2023, Plaintiffs refused to offer any clarification of the plain and ordinary meaning of any claim term. Defendant believes the Plaintiffs should be required to reveal now what they think that plain and ordinary meaning is, or be precluded from doing so later. Plaintiffs disagree with Defendant’s characterization of Plaintiffs’ position and will brief the issues of why the claim language speaks for itself and, therefore, the plain and ordinary meaning of the claim terms is sufficient and no further construction is warranted. Plaintiffs reserve the right to respond to arguments raised in the course of claim construction.

³ Defendant believes claim terms 4-9 (the “pharmacokinetics terms”) are indefinite for the same reasons and can be construed together. Plaintiffs disagree and believe that it would be more efficient to defer any issues of indefiniteness until later in the litigation.

No.	Term ¹	Plaintiffs' Construction	Defendant's Construction	Court's Construction
6	<p>“a plasma T_{max}”</p> <p>'444 patent: Claims 11, 13, 14, 69, 71, 74, 76</p>	Not indefinite; plain and ordinary meaning	Indefinite	
7	<p>“wherein the composition is formulated to achieve one or more of the following pharmacokinetic parameters:</p> <p>Pharmacokinetic Parameters Mean \pm SD C_{max} (pg/mL) 310 ± 54.3 T_{max} (hr)# 0.752 (0.251, 1.01) T_{last} (hr)# 7.00 (4.00, 12.01) AUC_{0-t} (pg*hr/mL) 949.89 ± 493.58 AUC_{0-inf} (pg*hr/mL) 1055.6 ± 513.61 AUC_{0-tau} (pg*hr/mL) 1053.2 ± 511.27 $t_{1/2}$ (hr) 2.30 ± 0.715 K_{el} (1/hr) 0.335 ± 0.127 $AUCR$ 0.892 ± 0.0369 CL/F (L/hr) 94.61 ± 51.09 $\ln(C_{max})$ 5.722 ± 0.1732 $\ln(AUC_{0-t})$ 6.740 ± 0.5206 $\ln(AUC_{0-inf})$ 6.855 ± 0.5063 $\ln(AUC_{0-tau})$ 6.853 ± 0.5050 # = T_{max} and T_{last} are presented as Median (minimum, Maximum)”</p> <p>'444 patent: Claim 69</p>	Not indefinite; plain and ordinary meaning	Indefinite	

No.	Term ¹	Plaintiffs' Construction	Defendant's Construction	Court's Construction
8	<p>“a net plasma AUC_(0-inf)”</p> <p>'444 patent: Claim 73</p>	Not indefinite; plain and ordinary meaning	Indefinite	
9	<p>“wherein the composition is formulated to achieve one or more of the following pharmacokinetic parameters:</p> <p>Pharmacokinetic Parameters Mean \pm SD C_{max} (pg/mL) 436 \pm 68.8 T_{max} (hr)# 0.507 (0.500, 1.00) T_{last} (hr)# 6.00 (4.00, 8.02) AUC_{0-t} (pg*hr/mL) 1003.0 \pm 383.45 AUC_{0-tau} (pg*hr/mL) 1080.3 \pm 408.57 t_{1/2} (hr) 1.69 \pm 0.425 K_{el} (1/hr) 0.437 \pm 0.124 CL/F (L/hr) 82.74 \pm 26.95 AI 1.12 \pm 0.353 ln(C_{max}) 6.065 \pm 0.1628 ln(AUC_{0-t}) 6.851 \pm 0.3623 ln(AUC_{0-tau}) 6.927 \pm 0.3581 # = T_{max} and T_{last} are presented as Median (minimum, Maximum)”</p> <p>'444 patent: Claim 74</p>	Not indefinite; plain and ordinary meaning	Indefinite	
10	<p>“said composition does not contain a chemical stabilizer”</p> <p>'333 patent: Claim 13</p>	Plain and ordinary meaning; i.e., said composition does not contain a composition which maintains the chemical stability of the peptide.	Does not contain a composition which maintains the chemical, biological or hormonal stability of the peptide.	

No.	Term ¹	Plaintiffs' Construction	Defendant's Construction	Court's Construction
11	"said subject has a bone fracture" '382 patent: Claim 8	Plain and ordinary meaning	Has a bone fracture when administration started (does not include a break that occurs after administration is started).	